JUST RIGHT 5000- 1.1% sodium fluoride toothpaste gel, dentifrice Elevate Oral Care

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Just Right 5000 - Spearmint

OTC - ACTIVE INGREDIENT SECTION

Sodium Fluoride 1.1% Anticavity toothpaste

INDICATIONS & USAGE SECTION

helps protect against cavities

WARNINGS SECTION

Keep out of reach of children under 6 years of age: if more than used for brushing is accidentally swallowed, get medical help or contact a poison control center right away.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children under 6 years of age:

INSTRUCTIONS FOR USE SECTION

Directions: *adults and children 2 years and older: wet a toothbrush and pump once to apply a pea-sized (~0.25 gram) amount of toothpaste onto a toothbrush * brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician. * to minimize swallowing, only pump once to dispense a pea-sized amount for children under 6 years. * supervise children's brushing until good habits are established. * children under 2 years: ask dentist or physician.

INACTIVE INGREDIENT SECTION

Inactive ingredients; Sorbitol, Water, xylitol, Glycerin, Hydrated silica, PEG-8, Spearmint Flavor, Sodium Lauryl Sulfate, Xanthan Gum, Potassium Phosphate, Sodium Benzoate, Sodium Saccharin, Mica, Menthol Crystals, FD&C Green NO.3.

OTC - QUESTIONS SECTION

Ouestions? 1-877-866-9113 or visit our website at www.elevateoralcare.com

OTC - PURPOSE SECTION

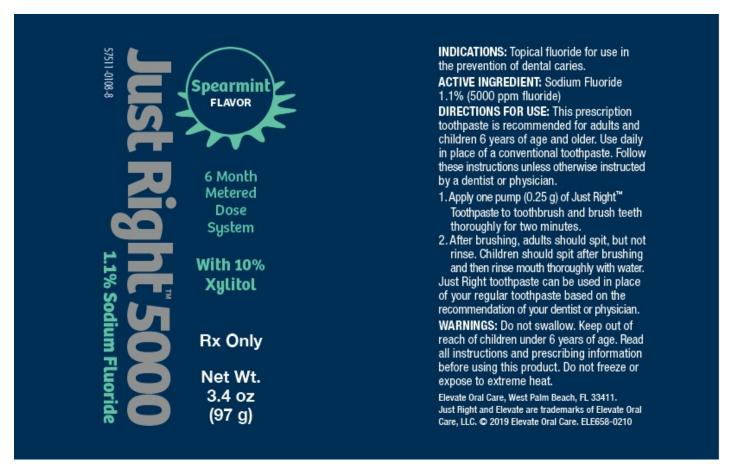
Helps protect against Cavities

DOSAGE & ADMINISTRATION SECTION

Directions: *adults and children 2 years and older: wet a toothbrush and pump once to apply a pea-sized (\sim 0.25 gram) amount of toothpaste onto a toothbrush * brush

thoroughly after meals or at least twice a day or use as directed by a dentist or physician. * to minimize swallowing, only pump once to dispense a pea-sized amount for children under 6 years. * supervise children's brushing untill good habits are established. * children under 2 years: ask dentist or physician.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



JUST RIGHT 5000

1.1% sodium fluoride toothpaste gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57511-0108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.1 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

SORBITOL (UNII: 506T60A25R)

HYDRATED SILICA (UNII: Y607T4G8P9)

GLYCERIN (UNII: PDC6A3C0OX)

FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)

SACCHARIN (UNII: FST467XS7D)

POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)

XANTHAN GUM (UNII: TTV12P4NEE)

SODIUM BENZOATE (UNII: OJ245FE5EU)

MICA (UNII: V8A1AW0880)

XYLITOL (UNII: VCQ006KQ1E)

PEG-8 DIMETHICONE (UNII: GIA7T764OD)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

Product Characteristics			
Color	blue	Score	
Shape	ROUND	Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

F	Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date		
1	NDC:57511- 0108-8	97 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2020	11/01/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2020	11/01/2023

Labeler - Elevate Oral Care (002863526)

Registrant - Elevate Oral Care (002863526)

Establishment					
Name	Address	ID/FEI	Business Operations		
Elevate Oral Care		002863526	repack(57511-0108)		

Revised: 11/2021 Elevate Oral Care